JUN 27 2014

5. 510(k) SUMMARY

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Lisa Giaquinto, Specialist, Regulatory Affairs
Phone: (610) 596-2354
Fax: (610) 266-4962
E-mail: lisa.giaquinto@bbraun.com

DEVICE NAME: Perican™ Ultra Needle

COMMON OR USUAL NAME: Anesthesia Conduction Needle
DEVICE
(An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.)

CLASSIFICATION: Class II, Product Code BSP, 868.5150

PREDICATE DEVICES: Contiplex® FX Continuous Nerve Block Set, Braun Medical Inc., K113059, Class II, CAZ, 868.5140.

Tuohy Sono, Pajunk GmbH, K113207, Class II, BSP, 868.5150

DESCRIPTION:

The B. Braun Perican Ultra needle is a single use, disposable anesthesia needle (18 Ga.) with Tuohy (curved) bevel. The needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or to facilitate the placement of a catheter. The proposed needle is composed of a hollow stainless steel cannula with 1 cm depth markings along the length of the cannula. The cannula is also designed with small 'echogenic' etched markings intended to enhance visibility of the needle when using an ultrasound imaging device. The cannula are secured to the winged polycarbonate hub using an epoxy resin and plastic spacer. The Perican Ultra needle is provided with a plastic stylet, which is pre-assembled inside the needle cannula. The hub is designed with a Luer adapter to facilitate attachment of the needle to anesthetic administration devices, such as a syringe.

INDICATIONS FOR USE:

The B. Braun Perican Ultra needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or to facilitate the placement of a catheter.

SUBSTANTIAL EQUIVALENCE:

Technological Characteristics

Predicate Device – Contiplex® FX (K113059)

The Perican Ultra needle is indicated for the same use (injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or to facilitate the placement of a catheter) and is similar in design to the Contiplex FX (17 Ga.) needle included as part of the Contiplex FX Continuous Nerve Block Set, cleared in 510(k) # K113059. The Perican Ultra needle is designed with the same stainless steel cannula, polycarbonate needle hub, spacer, adhesive, and guard materials as the Contiplex FX needles. The Perican Ultra needle differs from the predicate device in that the Perican Ultra needle is an 18 Ga. needle as opposed to 17 Ga., contains a stylet, and includes 'echogenic' etched markings to enhance visibility of the cannula under ultrasound, while the Contiplex FX needle does not include these features.

Predicate Device – Tuohy Sono (K113207)

The Perican Ultra needle is intended for the same use and is similar in design to the Tuohy Sono needles marketed by Pajunk GmbH. The Tuohy Sono needles are intended for the transient delivery of anesthetics to provide regional anesthesia and/or analgesia and/or to facilitate placement of a catheter. The needles may be used during all anaesthetic and analgesic procedures according to the physician's indication The cannulas consist of stainless steel tubing bonded to a polycarbonate hub using an epoxy glue. Like the Perican Ultra needles, the Tuohy Sono needles were cleared in a range of diameters (including 18 Ga.), are provided with a stylet, and include 'echogenic' markings to enhance visibility of the cannula under ultrasound.

Performance Testing

The following performance standards have been utilized in the evaluation of the Perican Ultra needle:

ISO 9626:1991/Amd. 1: 2001, "Stainless steel needle tubing for the manufacture of medical devices."

ISO 7864:1993, "Sterile hypodermic needles for single use."

ISO 594-1:1986, "Conical Fittings with a 6 % Luer taper for syringes, needles and certain other medical equipment – Part 1: General Requirements."

ISO 594-2:1998, "Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings."

Functional performance testing (summarized in Table 1) was completed with the proposed Perican Ultra needle to demonstrate that the needle performs as intended. Results of testing demonstrate that the Perican Ultra needle performs similarly to the predicate device and is substantially equivalent to the predicate devices.

Table 1: Performance Test Requirements

Requirement	Test
Visual Specifications	-Needles are free of hooks, burrs, cracks, damage, occlusion, foreign contamination discoloration, excessive roughness. -Inspected for presence of echogenic markings
Dimensional Specifications	The following dimensions are within specification according to the product drawing: -Cannula outer diameter -Cannula inner diameter -Cannula length -Distance to first depth marking -Depth marking width - Tip Gap of Stylet
Associate Device Testing	-Needle permits a 20 Ga. catheter to freely pass through the cannula -Needle performs adequately with sideport valve assembly (i.e. extension tubing) and threading assist guide attached
Ultrasound Visibility	-Needle is visible under ultrasound

Requirement	Test
Functional Testing	-The Luer of the needle meets the requirements of ISO 594-1 and ISO 594-2 -Needle is free of occlusions and permits flow of fluid -Needle assembly withstands a minimum pressure without leaking -Needle withstands bending without breaking -Needle is sufficiently stiff -Cannula to hub joint has sufficient tensile strength -Stylet fit in cannula is sufficient -Stylet to stylet hub has sufficient tensile strength
Sterilization	-SAL 10^{-6} -EO Residual Levels -LAL Bacterial Endotoxin Testing

Biocompatibility

The materials of construction of the Perican Ultra needle are either 1) non-patient contacting materials, 2) used in a predicate device with the same type and duration of patient contact, and/or 3) are patient contacting and have been evaluated for biocompatibility through testing, which meets and/or exceeds the tests recommended for consideration in ISO 10993-1: 2009, "Biological Evaluation of Medical Devices - Part 1: *Evaluation and Testing within a Risk Management Process*." The minimum tests completed with the Perican Ultra patient-contacting materials of construction are provided in Table 2: *Biocompatibility Test Requirements*.

Table 2: Biocompatibility Test Requirements

Requirement	Test
Biocompatibility	Cytoxicity, Intracutaneous Reactivity, Sensitization, Rabbit Pyrogenicity, Systemic Toxicity, USP <661> Physicochemical Tests for Plastics, Corrosion, Acidity/Alkalinity

Based on similarities to the predicate device and biocompatibility test results, the Perican Ultra needle materials of construction are considered biocompatible for their clinical application.

Conclusion

Results of functional performance and biocompatibility testing demonstrate that the Perican Ultra needle is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2014

B. Braun Medical, Inc.
Lisa Giaquinto, MS, RAC
Regulatory Affairs Specialist
901 Marcon Blvd.
Allentown, PA 18109

Re: K133632
Trade/Device Name: Perican™ Ultra Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 27, 2014
Received: May 29, 2014

Dear Ms. Giaquinto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133632

Device Name
Perican Ultra Needle

Indications for Use *(Describe)*
The B. Braun Perican Ultra needle is intended for use in injecting local anesthetics and/or analgesics into a patient to provide regional anesthesia and/or analgesia and/or to facilitate the placement of a catheter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Todd D Courtney -S
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